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NOTICE OF ALLOWANCE AND FEE(S) DUE

20995 7590 09/26/2008 KNOBBE MARTENS OLSON & BEAR LLP

2040 MAIN STREET FOURTEENTH FLOOR IRVINE, CA 92614

EXAMINER						
KOHARSKI, CHRISTOPHER						
ART UNIT	PAPER NUMBER					
3763 DATE MAIL ED: 09/26/2/	nna					

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.		
10/663,362	09/16/2003	Roger Massengale	IFLOW.149A	1650		
TITLE OF INVENTION: FLUID MEDICATION DELIVERY DEVICE						

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(8) DUE	DATE DUE
nonprovisional	YES	\$720	\$300	\$0	\$1020	12/26/2008

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. <u>PROSECUTION ON THE MERITS IS CLOSED.</u> THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown

B. If the status above is to be removed, check box 5b on Part B -Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail Mail Stop ISSUE FEE Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450

or Fax (571)-273-2885

INSTRUCTIONS: This appropriate. All further c indicated unless corrected maintenance fee notification	form should be used for correspondence includir d below or directed oth	or transmitting the I ng the Patent, advanc nerwise in Block 1, b	SSUE FEE and PUBLICA' e orders and notification of y (a) specifying a new corr	TION FEE (if requi maintenance fees w espondence address;	ired). I /ill be and/or	Hocks 1 through 5 sh mailed to the current (b) indicating a sepa	tould be completed where correspondence address as rate "FEE ADDRESS" for
INSTRUCTABLE FOR TICHICATIONS. CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)				Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.			
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IRVINE, CA 926	514		Γ				(Depositor's name)
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nonprovisional	YES	\$720	\$300	\$0		\$1020	12/26/2008
EXAMI	INER	ART UNIT	CLASS-SUBCLASS	7			
KOHARSKI, CI	HRISTOPHER	3763	604-890100	_			
"Fee Address" indic PTO/SB/47; Rev 03-02 Number is required. 3. ASSIGNEE NAME AN	ess an assignee is ident in 37 CFR 3.II. Comp	" Indication form ed. Use of a Custome A TO BE PRINTED C		gle firm (having as a agent) and the nam torneys or agents. If he printed. ype) patent. If an assign assignment.	memb es of u no nam ee is id	er a 2	ocument has been filed for
Please check the appropriate 4a. The following fee(s) a		categories (will not b	e printed on the patent): 4b. Payment of Fee(s): (Pl		_		up entity Government
☐ Issue Fee			A check is enclosed				
Publication Fee (No Advance Order - #	o small entity discount p	permitted)		☐ Payment by credit card. Form PTO-2038 is attached. ☐ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any			
			overpayment, to De	oosit Account Numbe	er	(enclose ar	extra copy of this form).
	SMALL ENTITY state	is. See 37 CFR 1.27.	b. Applicant is no lo				
NOTE: The Issue Fee and interest as shown by the re	l Publication Fee (if req ecords of the United Sta	uired) will not be acce tes Patent and Traden	epted from anyone other than nark Office.	the applicant; a regi	stered a	ittorney or agent; or th	e assignee or other party in
Authorized Signature				Date			
Typed or printed name				Registration N			
This collection of informa an application. Confidenti submitting the completed this form and/or suggestic Box 1450, Alexandria, Vi Alexandria, Virginia 2231	ation is required by 37 C iality is governed by 35 application form to the ons for reducing this bu- irginia 22313-1450. DC (3-1450.	FR 1.311. The inform U.S.C. 122 and 37 C USPTO. Time will verden, should be sent to O NOT SEND FEES O	nation is required to obtain or FR 1.14. This collection is e- vary depending upon the indo the Chief Information Offi DR COMPLETED FORMS	r retain a benefit by t estimated to take 12 i lividual case. Any co cer, U.S. Patent and TO THIS ADDRESS	he publ minutes mment Traden i. SENI	ic which is to file (and to complete, including s on the amount of tin ark Office, U.S. Depa O TO: Commissioner f	by the USPTO to process) g gathering, preparing, and he you require to complete atment of Commerce, P.O. for Patents, P.O. Box 1450,

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2040 MAIN STRE		ART UNIT	PAPER NUMBER		
FOURTEENTH FI IRVINE, CA 9261		3763			

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)

(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 586 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 586 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 (571)-272-4200.

Application No. Applicant(s) 10/663 362 MASSENGALE ET AL. Notice of Allowability Examiner Art Unit CHRISTOPHER D. KOHARSKI 3763 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS. This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308. This communication is responsive to 07/29/208. The allowed claim(s) is/are 1-2, 5-6, and 25-31. 3. Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) \square All b) ☐ Some* c) ☐ None of the: 1. T Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)). * Certified copies not received: _____. Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. THIS THREE-MONTH PERIOD IS NOT EXTENDABLE. A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient. CORRECTED DRAWINGS (as "replacement sheets") must be submitted. (a) Including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached 1) hereto or 2) to Paper No./Mail Date (b) including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d). 6. DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL. Attachment(s) 1. Notice of References Cited (PTO-892) 5. Notice of Informal Patent Application 2. Notice of Draftperson's Patent Drawing Review (PTO-948) Interview Summary (PTO-413), Paper No./Mail Date 3. Information Disclosure Statements (PTO/SB/08), 7. X Examiner's Amendment/Comment Paper No./Mail Date

U.S. Patent and Trademark Office PTOL-37 (Rev. 08-06)

of Biological Material

4. T Examiner's Comment Regarding Requirement for Deposit

9. ☐ Other .

8. X Examiner's Statement of Reasons for Allowance

Application/Control Number: 10/663,362

Art Unit: 3763

DETAILED ACTION

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Curtiss C. Dosier (Reg#46,670) on 09/17/2008.

IN THE CLAIMS

Please amend the claims as follows:

Claim 5. (Currently Amended) The delivery device of Claim [4] 1, wherein said at least one internal wall is defined by a seal between said impermeable layer and said semi-permeable layer.

Claims 7.-16. (Cancelled)

Allowable Subject Matter

Claims 1-2, 5-6 and 25-31 are allowed over the prior art of record as amended in the 07/22/2008 reply.

The following is an examiner's statement of reasons for allowance: The claims in this application have been allowed because the prior art of record fails to disclose either singly or in combination the claimed device of a fluid delivery device for transdermal delivery of fluid medications to patients; the device being formed from a thin envelope which is applied to a patient's skin. The envelope comprises at least one diffusion layer

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Art Unit: 3763

coupled to at least one impermeable layer such that at least one chamber exists therebetween. The delivery device also includes additional internal diffusion layers that create additional internal chambers and a valve positioned in the internal layer that facilitate filling the device with fluid, as well as connection of the device to external fluid sources.

The closest prior art of record is Reed, Jr. (USPN5,827,530) and Weston et al. (USPN4,605,399), however these references do not disclose the device as claimed or described above.

Regarding claims 1 and 28, the closest prior art of record fails to teach among all the limitations or render obvious the fluid medication delivery comprising a plurality of internal layers for fluid control located within the fluid reservoir.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher D. Koharski whose telephone number is 571-272-7230. The examiner can normally be reached on 7:30am to 4:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Date: 9/18/2008

/Christopher D Koharski/ Examiner, Art Unit 3763

/Nicholas D Lucchesi/ Supervisory Patent Examiner, Art Unit 3763